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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,039	12/20/2000	Raghu Raghavan	723.100US1	7943

7590 09/23/2004

Mark A. Litman & Associates, P.A.
York Business Center, Suite 205
3209 West 76th St.
Edina, MN 55435

EXAMINER

LU, TOM Y

ART UNIT

PAPER NUMBER

2621

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/745,039	RAGHAVAN ET AL.	
Examiner	Art Unit	
Tom Y Lu	2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 35-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment and written response filed on June 18, 2004 has been entered.
2. Claims 1, 11, 12, 14, 16, 18 and 35 are amended.
3. Claim 38 is newly added.
4. Claims 1-38 are pending.

Response to Arguments

5. Applicant's arguments, see Remarks, page 3, filed on June 18, 2004, with respect to Claims 1-3 have been fully considered and are persuasive. The rejection under 35 USC 101 of Claims 1-3 has been withdrawn.
6. Upon entry of the amendment, the objection of Claim 1 has been withdrawn.
7. Applicant's arguments filed on June 18, 2004 have been fully considered but they are not persuasive.

The Kucharczyk Reference:

Applicant argues the Kucharczyk reference teaches "viewing of the data in real time but teaches only visually estimation of the raw image. There is no computational modification/treatment of the data for specific purposes". In addition, Applicant alleges the visual observation has not substantive equivalence to the limitation of "for supplying a unified suite of quantification functionality for density functions defined in a three-dimensional space including two or more of the services..." as recited in Claim 1. In summary, applicant claims the rejection under 35 U.S.C. 102(e) cannot be sustained.

Upon further review of specification, and in light of applicant's arguments, the examiner respectfully disagrees for the following reasons. First of all, with regard to the statement of "viewing of the data in real time but teaches only visually estimation of the raw image. There is no computational modification/treatment of the data for specific purpose", the examiner would like to direct applicant's attention to column 23, lines 24-27 as well as figures 8, 9 and 10 in Kucharczyk, Kucharczyk explicitly teaches "diffusion as a function of distance from the injected substance can be represented as a series of curves denoting the concentration as a function of distance from the center of the cavity at successive time interval", the concentration of the injected substance is the claimed "density", which is clearly computationally estimated to be plotted as a curve shown in figure 8. And the concentration diffuses as the distance varies according to time. Therefore, there is computational modification/treatment of the image data for specific purpose of plotting a curve to demonstrate the diffusion of the injected volume in the tissue, column 23, lines 19-20. (Note the reason the examiner inserts the data is computationally estimated is the data for plotting the curve as shown in figure 8 must be obtained from the MRI image, and it is apparent to a person of ordinary skill in the art, the curve as shown in figure 8 is a work of computational modification of data. In addition, Kucharczyk in several occasions points out the MRI image system is a computer assisted system, for example, column 7, lines 35-36). Moreover, the allegation of not meeting claim language of "supplying a unified suite of quantification functionality for density functions defined in a three-dimensional space including two or more of the services..." has no ground. The first service of "computationally estimating of a rate of change of density with respect to time" is explained above, and also shown in figures 8, 9 and 10. The second service of "computationally estimating of a local or global rate at which

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material with a changing density is passing through a specified surface within the region or at a boundary of the region” is explained at column 11, lines 55-65, where the local rate is the change of the amplitude, and the global rate is the rate of diffusion, both rates change according to the amount of injected material to a specified surface within a region, such the surface region of is “a target anatomical location”, column 18, lines 61-62. Both rate changes are computationally estimated in order for the curve in figure 8, 9 or 10 to be plotted (Note the previous interpretation of local rate and global rate as “0.01 *ul*/min-10 *ul*/min” and “0.1-10 *ul*/min” is no longer proper due to the newly amended limitation of “computationally estimating”).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 1-34 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Kucharczyk et al (U.S. Patent No. 6,061,587).

- a. Kucharczyk discloses two services selected from the group consisting of: (a) computing of the volume of a region where a density lies above a specified threshold, below a specified threshold, or between two specified values; (b) computing of an integral of a density; (c) estimating of a rate of change of a density with respect to time; (d) estimating of a local or global failure of conservation of a superstate within the region represented by changes with time in

- density; (e) estimating of a local or global rate at which material within a changing density is passing through a specified surface within the region or at a boundary of the region; (f) and separating of density of a material into free and bound densities with a changing density (Kucharczyk teaches two services of “estimating of a rate of change of a density with respect to time” and “estimating of a local or global rate at which material with a changing density is passing through a specified surface within the region or at a boundary of the region”. See explanation in Paragraph 7 above. Note the claims dependent upon unselected services will not be examined), wherein an image is provided from the unified suite (see figure 8, 9 or 10).
- b. Referring to Claim 2, Kucharczyk teaches wherein the density function in at least one service varies in time (column 11, lines 34-36).
 - c. With regard to Claim 3, the claim is not examined because it is dependent upon one of the unselected services.
 - d. Referring to Claim 4, Kucharczyk discloses wherein service c is restricted to a specified region (column 18, lines 61-62, “a target anatomical location”).
 - e. With regard to Claim 5, the claim is not examined because it is dependent upon one of the unselected services.
 - f. Referring to Claim 6, Kucharczyk discloses wherein estimation of the global rate or local rate at which a superstrate with a changing density is passing through a specific surface is performed within an implemented transport model (see figure 2 for transport model).

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- g. Referring to Claim 7, Kucharczyk discloses wherein at least two services used in the method each yields an answer for restriction of a density to specified region (column 10, lines 22-25).
- h. Referring to Claim 8, Kucharczyk discloses wherein a density is obtained by a three-dimensional scanning process (column 22, lines 38-40).
- i. Referring to Claim 9, Kucharczyk discloses wherein a density is obtained by a numerical simulation process (column 11, line 65).
- j. Referring to Claim 10, Kucharczyk discloses wherein a density is obtained by an algorithm specification (column 11, line 65).
- k. With regard to Claim 11, the claim is not examined because it is dependent upon one of the unselected services.
- l. With regard to Claim 12, the claim is not examined because it is dependent upon one of the unselected services.
- m. With regard to Claim 13, the claim is not examined because it is dependent upon one of the unselected services.
- n. With regard to Claim 14, the claim is not examined because it is dependent upon one of the unselected services.
- o. With regard to Claim 15, the claim is not examined because it is dependent upon one of the unselected services.
- p. With regard to Claim 16, the claim is not examined because it is dependent upon one of the unselected services.

- q. With regard to Claim 17, the claim is not examined because it is dependent upon one of the unselected services.
- r. With regard to Claim 18, the claim is not examined because it is dependent upon one of the unselected services.
- s. With regard to Claim 19, the claim is not examined because it is dependent upon one of the unselected services.
- t. Referring to Claim 20, Kucharczyk discloses wherein said density comprises a concentration of a drug or other molecular substance in an organism (column 6, line 60).
- u. Referring to Claim 21, Kucharczyk discloses wherein said density refers to the concentration of a class of cell in an organism (column 6, line 63).
- v. Referring to Claim 22, Kucharczyk discloses wherein said density refers to the concentration of microscopic devices inserted to an organism (column 6, line 61).
- w. Referring to Claim 23, Kucharczyk discloses wherein said organism is a human body (see figure 1).
- x. With regard to Claim 24, see explanation in Claim 23.
- y. With regard to Claim 25, see explanation in Claim 23.
- z. With regard to Claim 26, see explanation in Claim 23.
- aa. With regard to Claim 27, see explanation in Claim 23.
- bb. With regard to Claim 28, see explanation in Claim 23.

- cc. Referring to Claim 29, Kucharczyk discloses wherein the density represents molecules, cells or devices inserted into an organism, body or brain for therapeutic purposes (column 6, lines 60-64).
- dd. Referring to Claim 30, Kucharczyk discloses wherein density is obtained by simulation of the transport and action of said molecule, cells or devices (column 9, lines 22-27).
- ee. Referring to Claim 31, Kucharczyk discloses wherein said density within the body, and said molecules or cells are part of a normal process of disease process (column 8, lines 25-26).
- ff. Referring to Claim 32, Kucharczyk discloses wherein said density refers to a material being transported by a geological process (column 8, lines 28-29).
- gg. Referring to Claim 33, Kucharczyk discloses wherein said density refers to a material moving through a structure created by human agency (see figure 2 for the structure).
- hh. Referring to Claim 34, Kucharczyk discloses wherein said density is a mathematical construct convenient in defining three-dimensional shapes for the purpose of computer aided design (column 7, lines 36-40).
- ii. With regard to Claim 38, Kucharczyk teaches the density functions defined dynamically in time (column 23, line 27 "time interval"), the rest of limitations are explained in Claim 1.

Conclusion

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

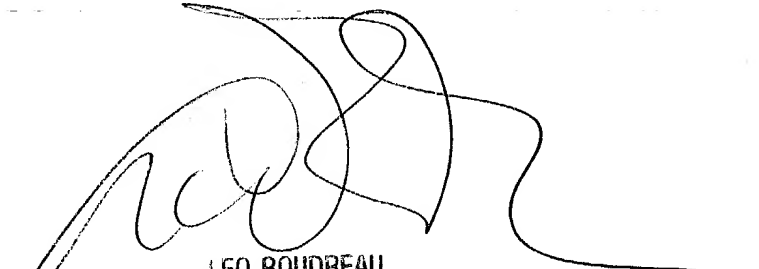
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tom Y Lu whose telephone number is (703) 306-4057. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tom Y. Lu



LEO BOUDREAU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2600